

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on October 12, 2005, the Examiner rejected claims 1-9 under 35 U.S.C. §103(a) as being unpatentable over Zohmann, U.S. Patent No. 6,558,353 in view of Sorenson et al. United States Publication No. 2002/0123723. The Examiner also rejected claims 1-9 under 35 U.S.C. §103(a) as being unpatentable over Zohmann in view of Yang (CN-2201946-Y). Accordingly, Applicant respectfully provides the following.

Claim Rejections under 35 U.S.C. §103(a).

To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2142.

Zohmann and Sorenson

**1. Zohmann in View of Sorenson Fails to Teach or Fairly Suggest the Claim**

**Limitations of the Present Application.**

Sorenson teaches an apparatus for specific interstitial or subcutaneous diffusion and dispersion of medication along the tubular element's length. Sorenson, abstract. Accordingly, Sorenson discloses a method of administering medicine along the entire length of the needle inserted into a

patient. Use of Sorenson's needle and its release of drugs along the entire length of the needle produces a dangerous situation if utilized to administer drugs to block peripheral nerves as claimed by the present application.

In contradistinction the peripheral nerve block needle of the present application is designed such that "fenestrations 20 are peripherally located proximate a distal end 16 of a needle 12." Specification, pg. 7, lns. 12-22. The importance of localizing the fenestrations near the distal end of the needle is elucidated by disclosure on page 8 of the specification which indicates that "fenestrations are preferably located within one or two millimeters, and most preferably within 0.17 inches of each other for this purpose," wherein said purpose is to "deliver drug approximate to the lower extremity nerves which comprise only a few millimeters in width, for example a discrete compartment of only a few millimeters is located between the semitendinosus muscle 32 and bicep femoris muscle 34. This facial compartment 30 houses the sciatic nerve 36, one of two major lower extremity nerves, fenestrations 20 are spaced at relatively small intervals along the needle 12 in order to maximize an even distribution of local anesthetic to any particular facial compartment 30, including particularly male compartments such as the housing of the sciatic nerve 36." Specification, pg. 8, lns. 7-17.

In light of the Examiner's rejection, Applicant amended independent claims 1, 5 and 7, adding the limitation that the fenestrations are isolated on a distal end of the fenestrated needle. This is very different than the plurality of perforations disclosed in Sorenson that release anesthetics along its entire length so that it uniformly disperses medication to a treatment zone. Sorenson pg.3 ¶ 33. Sorenson specifically differentiates itself from the "point-source" fluid

introduction of other devices. In contrast to the broad, uniform release strategy of Sorenson, the present invention focuses on precisely placing its injections in order to avoid intravascular injection and/or inadvertent penetration of a nerve. Specification, pg. 3, lns 20-22. Thus, it would be dangerous to apply the teachings of Sorenson to the present invention, as application of Sorenson's invention would likely send anesthetic outside the boundaries of the well defined facial compartments in which Applicant directs the anesthetic. Therefore, because the combination of Zohmann and Sorenson does not teach every limitation of the claimed invention, Applicant respectfully requests that the Examiner withdraw his Section 103 rejection.

## **2. The Prior Art Teaches Away from Combining Zohman with Sorenson**

The present application teaches a method of administering localized anesthesia to block peripheral nerves. Zohman with Sorenson would destroy Zohmann's needle's capacity to deliver localized administrations of anesthesia. Sorenson discloses an apparatus with fenestrations along the entire length of the needle, while Zohman discloses only a single port. Zohman was specifically designed to administer anesthesia to localized areas of a patient's body. Excessive administration outside the localized region may result in damage to surrounding tissues, and may additionally fail to localize anesthesia to the desired area. Accordingly, combining Sorenson with Zohmann produces an apparatus which is incapable of administering anesthesia to a localized region as is necessarily taught and claimed by the present application.

**3. Zohmann in View of Yang**

Yang discloses a needle with three side ports. As indicated above, because Yang discloses a method of releasing anesthetic along the entire length of the needle the combination of Zohmann and Yang fail to read on the claims of the present application.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,



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